UNITED STATES DISTRICT COURT
DISTRICT OF MINNESOTA

In re Bair Hugger Forced Air Warming Products Liability Litigation	MDL No. 15-2666 (JNE/FLN)
This Document Relates to All Actions	**PLAINTIFFS' MEMORANDUM OF LAW IN SUPPORT OF MOTION FOR LEAVE TO AMEND MASTER LONG FORM AND SHORT FORM COMPLAINTS TO ADD CLAIM FOR PUNITIVE DAMAGES**

TABLE OF CONTENTS

Page

LEGAL STANDARD 1

ARGUMENT 3

1. Defendants Failed to Validate the Safety of the Bair Hugger 5

2. Defendants Secretly Reduced the Filtration Efficiency of the Device 11

3. Defendants Know the Device is Contaminated with Bacteria 15

4. Defendants Know of Scientific Literature Finding Infection Risks 24

5. Defendants Know the Literature They Cite Has Significant Limits 30

6. Defendants Manipulated Scientific Research for Commercial Gain 32

7. Defendants Repeatedly Refused to Conduct a Contamination Study 36

8. Defendants Willfully Suppressed Potentially Harmful Testing 41

9. Defendants Deliberately Failed to Warn of a Known Risk 44

10. Defendants Cannot Challenge the Facts in this Memorandum 46

CONCLUSION 47

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Plaintiffs submit this Memorandum in Support of their Motion for Leave to Amend their Master Long Form and Short Form Complaints to Add a Claim for Punitive Damages. The facts presented below provide *prima facie* evidence that 3M Company and Arizant Healthcare, Inc. ("Defendants" or "the company") deliberately disregarded patient safety.

LEGAL STANDARD

A transferee court overseeing multidistrict litigation may grant a motion to amend to add a claim for punitive damages. *See, e.g.*, *In re Levaquin Prod. Liab. Litig.*, MDL No. 08-1943, 2014 WL 11395078, at *6 (D. Minn. 2014). At this stage, the Court need not "determine the extent to which, if at all, any other state's law relative to punitive damages would apply to any particular plaintiff's claims." *See id.* When considering a motion to amend to assert a claim for punitive damages, the Court should look to the procedural requirements outlined in Minnesota statutes. *In re Levaquin Prod. Liab. Litig.*, MDL No.

08-1943 (JRT), 2010 WL 7852346, at *6–10 (D. Minn. 2010). As Chief Judge Tunheim explained in the Levaquin MDL, "Minnesota Statute § 549.20 is a remedial provision to which a conflict of law analysis does not apply." *Id.* at *10. Even if the statute were not remedial in nature, "Minnesota's [conflict of law analysis] would dictate the application of Minnesota law to the issue of punitive damages in this [multidistrict litigation]." *See id.*

Minnesota law permits an award of punitive damages upon a showing that the defendant deliberately disregarded the rights or safety of others. *See* Minn. Stat. § 549.20, subd. 1. This occurs where, as here, the defendant "has knowledge of facts or intentionally disregards facts that create a high probability of injury to the rights or safety of others" and "deliberately proceeds to act in conscious or intentional disregard of the high degree of probability of injury to the rights or safety of others" or "deliberately proceeds to act with indifference to the high probability of injury to the rights or safety of others." *See id.*

On a motion to amend the complaint to assert a punitive damages claim, however, the standard is much lower. *See, e.g., id.* at *6. Plaintiffs "need not demonstrate an entitlement to punitive damages *per se*, but only an entitlement to allege such damages." *Berczyk v. Emerson Tool Co.*, 291 F. Supp. 2d 1004, 1008 (D. Minn. 2003). Plaintiffs need only offer *prima facie* evidence, which, if unrebutted, could support a finding of deliberate disregard for the rights or safety of others. *See In re Levaquin*, 2010 WL 7852346, at *6; *see also Tousignant v. St. Louis Cnty.*, 615 N.W.2d 53, 59 (Minn. 2000) ("[A] *prima facie* case simply means one that prevails in the absence of evidence invalidating it.") (internal citations omitted). Accordingly, in determining whether to grant Plaintiffs' motion, "the

Court makes no credibility rulings, and does not consider any challenge, by cross-examination or otherwise, to [Plaintiffs'] proof." *Berczyk*, 291 F. Supp. 2d at 1008 n.3.

ARGUMENT

Like here, plaintiffs in the Levaquin MDL moved to amend their complaint to add a claim for punitive damages. In granting the motion, Chief Judge Tunheim explained that if the plaintiffs' evidence was fully believed and accepted as true, a jury could reasonably infer that the defendants had: (1) knowledge of or intentionally disregarded medical research regarding Levaquin's tendency to cause injury; (2) manipulated scientific studies to produce commercially favorable results; (3) failed to adequately warn the plaintiffs and their doctors of the dangers of Levaquin, despite knowing the particular risks of using the drug; and (4) affirmatively misrepresented Levaquin's safety profile to the public through their marketing campaign and other tactics. *See In re Levaquin*, 2010 WL 7852346, at *10.

Judge Noel likewise granted a motion to add claims for punitive damages in the Mirapex MDL. In doing so, Judge Noel relied on the plaintiffs' *prima facie* evidence that the defendants had: (1) failed to properly research the dangers of the product and to warn patients about the same; (2) publicly denied there was a causal link between the product and those dangers; (3) failed to report important information about the product to the FDA; (4) delayed conducting a study on the product; and (5) suppressed additional research on the product. *In re Mirapex Prod. Liab. Litig.*, 2007 WL 9636345, at *6–9 (D. Minn. 2007).

The conduct at issue in this MDL is similar in every respect. Through this motion, Plaintiffs offer *prima facie* evidence regarding each of the following deliberate actions:

- Defendants designed and marketed the Bair Hugger without performing any safety validation with respect to the known risk of airborne contamination.

- Defendants not only secretly cut the efficiency of the Bair Hugger filter without validating the safety of the new filtration level, but they hid this change from the FDA, healthcare providers, and the public.

- Defendants knew the inadequate filter would result in increased particles passing through the filter, causing internal contamination of the Bair Hugger.

- Defendants' product engineers repeatedly developed feasible design changes that would have reduced, if not eliminated, the risk of internal contamination, but all of these changes were rejected by management.

- Defendants willfully disregarded medical research regarding the potential for the Bair Hugger to harm patients through disruption of the surgical field.

- Defendants were aware of the weaknesses and limitations of the research they used to support the Bair Hugger but never warned the public of the same.

- Defendants engineered and manipulated scientific research to produce commercially favorable results.

- Defendants prevented, discredited, and suppressed scientific inquiry regarding the potential for the Bair Hugger to increase the risk of orthopedic infections.

- Defendants affirmatively misrepresented the safety of the Bair Hugger and failed to warn customers, healthcare providers, and the public of those risks.

Viewed collectively or independently, this conduct shows that Defendants knew the Bair Hugger posed a serious safety risk to orthopedic patients but deliberately acted with intentional disregard to the high probability of injury to patients. *See* Minn. Stat. § 549.20.

Indeed, among other patient safety risks, Defendants knew the Bair Hugger could disrupt the sterile surgical field and mobilize pathogens to the surgical site. They also knew that the device could harbor dangerous pathogens, adding bioburden to the sterile surgical environment. Though Defendants knew that either one of those mechanisms could cause deep joint infections in orthopedic patients, they ignored, suppressed, and distorted the evidence. *See In re Mirapex*, 2007 WL 9636345, at *1, *14 (granting plaintiffs' motion to add claim for punitive damages because defendants "ignored" evidence of safety risks and "attempted to suppress" the evidence rather than warning patients of "possible side effect").

1. Defendants Failed to Validate the Safety of the Bair Hugger.

When the company first developed the Bair Hugger in 1987, it submitted a 510(k) notification to the FDA identifying a substantially equivalent predicate device. The company claimed the Bair Hugger was "similar in design and function to the Sweetland Bed Warmer and Cast Dryer," a product manufactured by the J.T. Posey Co. from 1937 to 1942.[1] Like the Sweetland Bed Warmer, the 510(k) application for the Bair Hugger Model 200 made clear that the device was intended solely for use outside the operating room to treat post-operative hypothermia.[2] Since that time, each and every model of the Bair Hugger, including the Bair Hugger 505, 750, and 775, has been intended for intraoperative use even though the original predicate devices were not designed to be used in that manner.[3]

[1] Exhibit 1 to the Declaration of Genevieve M. Zimmerman (hereinafter "Exhibit 1"), 1987-09-14 510(k) Notification Letter – 3MBH00047858–67.
[2] *Id.* at 3MBH00047859.
[3] *See, e.g.*, Exhibit 2, 1996-01-10 510(k) Summary of Safety & Effectiveness – 3MBH00047382–83.

Plaintiffs' expert Dr. Yadin David, the Chairman of the FDA's Medical Device Good Manufacturing Practices Advisory Committee, explained in his report that unlike Class III devices, which require a "rigorous approval process," the primary responsibility for safety validation for Class II devices like the Bair Hugger lies with the manufacturer.[4] While "the FDA relies on the assurances of the manufacturer that appropriate performance testing and validation has occurred,"[5] the former Director of Research and Development and later CEO of the company, Gary Maharaj, testified to an utter lack of safety validation testing. **He could not recall any testing carried out during the development of the early Bair Hugger Model 500 series to support the "assertion that airborne particles were not a problem"[6] despite the well-established link between particles and infections.[7]**

Corporate Representative Al Van Duren confirmed the same, unequivocally testifying that "the company is unaware of any biological testing during the design of the [Bair Hugger Model] 505."[8] Likewise, Teri Woodwick-Sides, Vice President of Product Development, testified that no product testing had ever occurred with regard to the Bair Hugger and airborne contamination.[9] Former Regulatory Compliance Manager, David Westlin, also testified that the company had not done any testing as to that safety issue.[10]

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[4] Exhibit A, Report of Dr. Yadin David at 17.
[5] *Id*. at 18.
[6] Exhibit 3, Deposition of Gary Maharaj at 97:3–15 (emphasis added).
[7] *See* Exhibit B, Report of Dr. William Jarvis at 14–15; *see also* Exhibit 4, Proceedings of the International Consensus Meeting On Periprosthetic Joint Infections at 115–116.
[8] Exhibit 5, Deposition of Corporate Representative Al Van Duren at 49:13–18; 51:5–16.
[9] Exhibit 6, Deposition of Teri Woodwick-Sides at 57:20-59:10.
[10] Exhibit 7, Deposition of David Westlin at 117:18–24.

The same held true with respect to the Model 750. The company's corporate representative admitted he could not recall "whether any safety testing" was conducted,[11] while Karl Zgoda, the Project Leader for the Model 750, testified he was not aware of any validation testing to assure the device was safe with respect to airborne contamination:

> Q. In validating the 750, what testing did you rely on?
>
> A. As far as validating the device?
>
> Q. As far as this, prevention of airborne contamination. What testing did you rely on to assure us that the unit was safe?
>
> A. **I would say – I'm not aware of any verification testing that was done internal to the company to verify this.**[12]

Nor could Mr. Zgoda recall the issue of airborne contamination being discussed by anyone at the company during the development of the Model 750.[13] Furthermore, Mr. Van Duren testified that particulate levels were never measured before the product was sold:

> Q. Before the 750 was ever released and sold and used on a patient, what was done to ensure that that change in air output had no adverse effect on airborne contamination issues?
>
> A. **Well to my knowledge there were no tests that looked at airborne particulate levels with the new device before it went on the market.**[14]

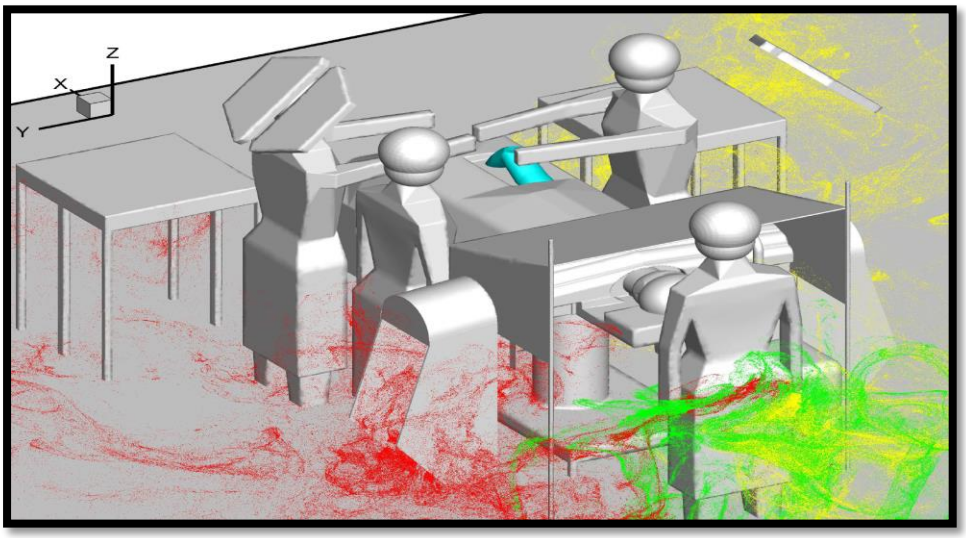
[11] Exhibit 5, Deposition of Corporate Representative Al Van Duren at 87:16-89:20.
[12] Exhibit 8, Deposition of Karl Zgoda at 42:22-43:5 (emphasis added).
[13] *Id.* at 39:20.
[14] Exhibit 5, Deposition of Corporate Representative Al Van Duren at 90:22-91:3 (emphasis added).

While such testing was never performed by Defendants before marketing the device, it was recently performed by Plaintiffs' expert Mr. Michael Buck, an expert in air quality investigations who has worked in the Department of Environmental Health and Safety at the University of Minnesota for over two decades.[15] This test involved measuring particles produced from both new and used Bair Hugger units using a laser optical particle counter in a laboratory clean room.[16] As stated in Mr. Buck's report, "[t]he evaluations showed clearly the Bair Huggers – through all operational modes – demonstrated increased production of particles from internal and/or external sources."[17] Mr. Buck thus concludes that both used and new Bair Hugger units cause "an increase in the number of particles in the operating room, and in particular, in close proximity to the surgical site."[18] This creates an alarming patient safety issue because increased particles increase the risk of infection.[19]

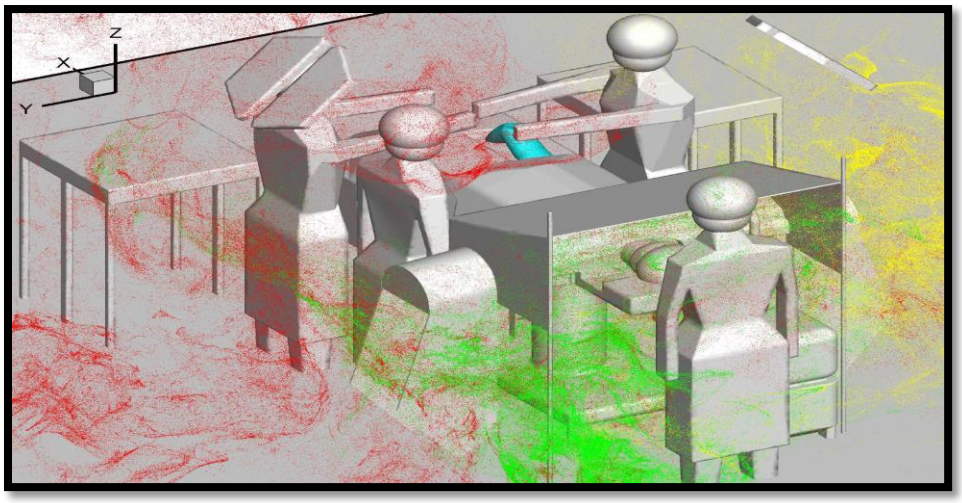
Moreover, Plaintiffs' expert Dr. Said Elghobashi recently performed computational fluid dynamic modeling at the University of California, Irvine to create a "large-eddy simulation (LES) of the interaction between the ventilation air flow and forced hot air from a [Bair Hugger] blower."[20] The results indisputably show that "hot air from the blower and the resultant thermal plumes are capable of lifting the particles and transporting them to

[15] Exhibit C, Report of Mr. Michael Buck at 3.
[16] *Id.* at 7–16.
[17] *Id.* at 17.
[18] *Id.*
[19] *See* Exhibit B, Report of Dr. William Jarvis at 14–15; *see also* Exhibit E, Report of Dr. Jonathan Samet at 14–17.
[20] Exhibit D, Report of Dr. Said Elghobashi at 2.

the side tables, above the operating table, and [to] the surgical site."[21] Imaging from the computational simulation further shows particles entering the area of the surgical incision:



(Scatter plot of particles with Bair Hugger turned off. Exhibit D at 50, Fig. 24(a)).



(Scatter plot of particles with Bair Hugger turned on. Exhibit D at 50, Fig.24(b)).

If Defendants had performed proper validation testing prior to marketing the Bair Hugger, they would have found the same patient safety issue. After all, Defendants had

[21] *Id.* at 62 (lines 825–27).

warned of the risk of airborne contamination in the labeling of the Model 200,[22] but they removed that warning on later models, including the Model 505. Project Leader Karl Zgoda further testified that he ultimately regrets not performing adequate safety validation testing:

> Q. If you had to do it over again, if we could turn back the hands of time and go back to developing the 750 again, you'd want to make sure these tests were done; wouldn't you?
>
> A. A lot of things are obvious in hindsight, but given where we're sitting today, yes, **it probably would have been prudent to do them**, but they were not on my radar to do, so.[23]

This evidence supports Plaintiffs' "contention that, had reasonable research or testing been performed, the risk could have been foreseen." *Smith v. Louisville Ladder Co*., 237 F.3d 515, 532 (5th Cir. 2001) (internal citation omitted). It also shows, as discussed in Dr. Yadin David's expert report, that Defendants deliberately disregarded patient safety by failing their "obligation under the regulations to perform adequate safety validation prior to marketing the device."[24] *See In re Mirapex*, 2007 WL 9636345, at *10 (concluding that defendant's failure to study side effects "establish[ed] a *prima facie* case that [it] acted with disregard for the high probability of injury to the rights and safety of others"). While this single irresponsible act could alone justify an award of punitive damages, it was just the start of nearly 20 years of willful and reckless conduct that put millions of patients at risk.

[22] *See* Exhibit 9, Photograph of Warning Label on Inside Cover of Bair Hugger Model 200.
[23] Exhibit 8, Deposition of Karl Zgoda at 205:11–18 (emphasis added).
[24] Exhibit A, Report of Dr. Yadin David at 44.

2. Defendants Secretly Reduced the Filtration Efficiency of the Device.

In contrast to Defendants' representations to the Court, Defendants' Corporate Representative admitted that the filter of the Bair Hugger is not just intended to protect the motor of the device; rather, the filter plays an important safety function given the link between particulates and infections.[25] Indeed, one of the express purposes of the filter "is to reduce the particulates that enter and exit the Bair Hugger."[26] When the Bair Hugger 505 was first introduced and marketed for operating room use in 1996, Defendants did not equip the device with a HEPA filter, which would have prevented 99.97% of particles 0.3 microns and larger from entering and likely contaminating the device. Defendants instead decided to equip the device with an M10 filter that was only "93% efficient at 0.2 microns."[27] The Bair Hugger Model 505 was cleared for sale by the FDA based on Defendants' assurances regarding the M10 filter. For example, in the "Summary of Safety and Effectiveness" for the Model 505, Defendants assured the FDA that the M10 filter, which it called a "high efficiency filter," would safeguard against airborne contamination.[28]

When Defendants developed the Bair Hugger Model 750 in early 2000, their engineers encountered a problem. As explained by Dr. Yadin David, "the company intended that the unit have a HEPA or near-HEPA performance filter" and "wanted to at

[25] *See* Exhibit 5, Deposition of Corporate Representative Al Van Duren at 49:2–18; *see also* Exhibit B, Report of Dr. Williams Jarvis at 14–15.
[26] *See* Exhibit 5, Deposition of Corporate Representative Al Van Duren at 25:10–13; *see also* Exhibit B, Report of Dr. Williams Jarvis at 14–15.
[27] Exhibit 10, 2008-08-04 Internal Email – 3MBH00022373.
[28] Exhibit 2, 1996-01-10 Summary of Safety & Effectiveness – 3MBH00047382.

least maintain the efficiency of the Model 505 filter, which at that time was around 95%."[29] However, internal testing showed that neither a HEPA filter nor the M10 filter would work on the Model 750.[30] The company thus decided to use an inferior filter, known as the M20 filter, which "reduced the efficiency of the filter from 95% to below 50% at .2 microns."[31]

Dr. David's report explains how Defendants concealed this change from the FDA:

> [O]n June 1, 2000, the company wrote a letter to the FDA making an amendment to the 510(k) submission. The company noted that it had originally planned to use a HEPA filter on the device. However, the company told the FDA that "we cannot obtain the new, higher efficiency HEPA filter media from our supplier at this time." Therefore, the company stated it wanted "to amend the 510(k) to include a filter that is substantially equivalent to the filter currently being used in all of our cleared devices." The amendment claimed that [the] Bair Hugger 750 would "use our current filter characteristics." **The company made this statement to the FDA while its engineers were privately acknowledging that they could not make the Model 750 function properly using the high-efficiency 0.2 micron filter that was substantially equivalent to the filter of the Model 505.**[32]

Despite the assurances made to the FDA, Defendants secretly used the M20 filter with inferior characteristics and reduced efficiency.[33] This change allowed the Bair Hugger to produce a target airflow of 40 cubic feet per minute, far greater than the 23-25 cubic feet per minute of the Model 505.[34] Yet a 2003 email shows Defendants were aware of the legal requirements for validating any reduction in the level of filtration. In the email, Defendants' Director of Research and Development and the Director of Regulatory Affairs jointly

[29] Exhibit A, Report of Dr. Yadin David at 21.
[30] *Id.*
[31] *Id.* at 22 (citing 3MBH00022367).
[32] *Id.* (emphasis added).
[33] *Id.* at 21.
[34] Exhibit 11, 2000-05-01 Internal Design Notes – 3MBH01735812.

recognized that "we must either match 505-level filtration or prove that reduced filtration is still safe."[35] They understood that "[t]his proof would take the form of biological comparison testing between old and new units," and "if this testing is successful, a letter-to-file is necessary."[36] Dr. David discusses the regulatory implications of this discussion:

> A letter-to-file is created when a manufacturer makes a non-significant change to an existing legally-marketed product and creates internally documented justifications showing the reasons for change and test results that demonstrate why the change does not impact the safety level or the efficacy of the product. . . . When a manufacturer makes a change, it must use one of two forms of compliance with this FDA requirement: (1) letter-to-file when the change is not significant, or (2) submit to the FDA special 510(k) submission or PMA supplement when the change is significant. In either form the manufacturer must demonstrate that the change did not impact safety or efficacy of the device.
>
> In this case, the Defendant[s] drastically cut the level of filtration by using new filter media, but according to the [Defendants'] corporate representative, there was nothing done in terms of "safety validation either internally or externally on the issue of reduced filtration and potential airborne contamination." In addition, the Defendant[s] "did not do any testing with respect to whether or not contaminants inside the machine could ultimately migrate to the surgical field." Internal documents also confirm that the Defendant[s] never conducted any lifecycle performance testing on the filter, having never allowed a unit "to operate for one year or 500 hours of use and then verifying its tolerances and performance." **Ultimately, my review showed that the filter change was never disclosed to the FDA.**[37]

Soon after these events, Defendants learned the filter supplier could no longer provide replacement filters for the older Model 505 units still in service, so Defendants secretly reduced the filter efficiency of those devices well.[38] Defendants never conducted

[35] Exhibit 12, 2003-08-26 Internal Email – 3MBH01031246.
[36] *Id.*
[37] Exhibit A, Report of Dr. Yadin David at 23–24 (emphasis added) (citations omitted).
[38] *Id.* at 25.

safety validation testing for the Model 505 or 750; nor did they inform the FDA. Dr. David explains how Defendants disregarded their duties when making this critical design change:

> When a manufacturer makes a change in the device's components, the hazard analysis needs to be updated. According to the FDA regulation 21 CFR 820.39(i), this requires that "Each manufacturer shall establish and maintain procedures for the identification, documentation, validation or where appropriate verification, review, and approval of design changes before their implementation." The objective of the program – hazard mitigation and control – is maintained for the purpose of preventing production of defective devices that can endanger consumers and preventing hazardous devices from reaching the market. The evidence I have reviewed indicates that the **Defendant[s] failed to meet these obligations when changing safety components and performance of the device, recklessly endangering patients in the process.**[39]

To make matters worse, as revealed during a 2009 facility inspection, the FDA continued to believe that the Bair Hugger used a "HEPA filter" as a "secondary safeguard against contamination."[40] Yet Defendants never corrected this false information.[41] They deliberately concealed the "actual filtration level" from the FDA and willfully withheld the same information from its customers, even in response to direct inquiries.[42] Company executives made it crystal clear they did "not want to disclose the actual filtration level."[43]

Failing to inform the FDA of these material changes, while further hiding them from healthcare providers and the public, "constitutes a *prima facie* case that [Defendants] acted with deliberate disregard for the risks or safety of others." *In re Mirapex*, 2007 WL

[39] *Id.* (emphasis added).
[40] Exhibit 13, 2010-11-17 FDA Establishment Inspection Report – 3MBH00048072.
[41] Exhibit A, Report of Dr. Yadin David at 25.
[42] *See* Exhibit 14, 2012-03-16 Internal Email – 3MBH00132832; *see also* Exhibit 15, 2013-10-07 Internal Email – 3MBH00126140.
[43] Exhibit 14, 2012-03-16 Internal Email – 3MBH00132832.

9636345, at *10; *see also id.* at *12–13 (allowing plaintiff to plead punitive damages claim in part because defendant omitted important information in correspondence with FDA); *In re Levaquin*, 2010 WL 785234, at *10 (failure to inform public of risks and misrepresenting safety profile of drug was *prima facie* evidence of deliberate disregard for public safety).

3. Defendants Know the Device is Contaminated with Bacteria But Rejected Numerous Proposals to Solve this Patient Safety Problem.

After silently slashing the filtration efficiency of the Bair Hugger, the company received reports from a variety of sources indicating the presence of dangerous bacteria inside the device—a "problem" according to the company's clinical consultant, Dr. Daniel Sessler.[44] For example, in a study published in INFECTION CONTROL AND HOSPITAL EPIDEMIOLOGY entitled *Persistent Acinetobacter baumannii? Look Inside Your Medical Equipment*, the authors evaluated medical equipment involved in an outbreak of dangerous infections.[45] They found contaminated particles in the interior of a Bair Hugger containing pathogens that were isolated to the same strain of bacteria responsible for the outbreak.[46]

In response to customer concerns regarding that study, additional articles,[47] and customer reports of contaminated units, the company acknowledged that bacteria had been cultured from inside Bair Hugger units.[48] Yet Clinical Director Al Van Duren

[44] Exhibit 16, Deposition of Dr. Daniel Sessler at 64:21–23.
[45] Exhibit 17, 2004-11-01 Bernard Study – 3MBH00018429.
[46] *Id.*
[47] Exhibit 18, 2009-03-04 Internal Email – 3MBH00024633 (Defendants learned that a hospital had discovered bacteria inside of a Bair Hugger); Exhibit 19, 2009-08-02 Internal Email – 3MBH00024678 (Defendants learned that 12 of 29 units tested positive for pathological growth. The researchers recommended adding a HEPA filter to the device.).
[48] Exhibit 20, 2006-11-01 Customer Letter – 3MBH00008941.

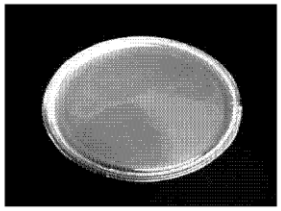
unhesitatingly assured customers that there was no infection risk if the "Bair Hugger system is used and maintained properly."[49] He made this public representation in the face of several ongoing projects to address the safety risks of internal contamination even though the company had refused to conduct testing or to provide warnings of that very risk.

In 2008, Defendants began the first major project to address the internal contamination issue, known as "Project Ducky."[50] Teri Woodwick-Sides, former Vice President for Product Development, acknowledged there were technological solutions for eliminating bacteria inside the Bair Hugger.[51] Indeed, in Project Ducky, a select group of executives worked with a design firm to develop a Bair Hugger prototype with a HEPA filter and antimicrobial coating on the hose.[52] Because Defendants intended to solve the "perception as well as the **presence of bacteria**"[53] by ultimately "achiev[ing] cleanliness" of the unit,[54] they researched numerous ways of filtering and eliminating bacteria with "antimicrobial agents."[55] But given the dearth of internal testing and without any knowledge of what level of filtration was safe, Defendants asked the most basic questions: "How much bacteria can be allowed to pass through?" and "How much is dangerous?"[56] Despite degrading the filtration efficiency of the device, Defendants decided that HEPA

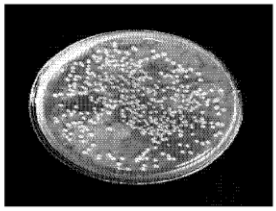
[49] *Id.*
[50] Exhibit 21, 2009-05-20 PowerPoint Presentation – 3MBH00022625.
[51] *See* Exhibit 8, Deposition of Teri Woodwick-Sides at 127:19.
[52] Exhibit 21, 2009-05-20 PowerPoint Presentation – 3MBH00022625.
[53] *Id.* at 3MBH00022629 (emphasis added).
[54] *Id.*
[55] *Id.* at 3MBH00022642–47.
[56] Exhibit 22, Internal Document re Filtration Topics – 3MBH00022877.

filtration was the target.[57] After months of development and testing, Defendants developed a prototype which integrated a cylindrical HEPA filter into the hose at the blower outlet.[58]

Defendants also developed antimicrobial treatments for the hose of the Bair Hugger despite their representation that "none of the materials used in the warming hose . . . support the growth of any known bacteria."[59] During Project Ducky, Defendants learned that the Bair Hugger hose was extraordinarily hospitable to growth of dangerous bacteria. In an "Antimicrobial Assessment Report," an independent company added "100,000 bacterial colony forming units" to the Bair Hugger hose.[60] After 24 hours, "there were **over 3 million** bacterial colony forming units per ml of solution in contact with the unenhanced hose."[61] When the same process was conducted with a bacterial coating inside the hose, the testing showed "after 24 hours there were less than 100 bacterial colony forming units per ml."[62]



With IonArmour®



Without IonArmour®

The growth on the plate on the right is from a 10^4 dilution of inoculum and occurs with unenhanced Bair Hugger 700 hose samples, indicating that after 24 hours there were over 3 million bacterial colony forming units per ml of solution in contact with the unenhanced hose, from a starting concentration of around 100,000 bacterial colony forming units. The lack of growth on the plate on the left, from a 10^2 dilution of inoculum, occurs with IonArmour®-enhanced Bair Hugger 700 hose samples and indicates that after 24 hours there were less than 100 bacterial colony forming units per ml of solution in contact with the IonArmour®-enhanced hose.

[57] Exhibit 21, 2009-05-20 PowerPoint Presentation – 3MBH 00022634.
[58] *Id.*
[59] Exhibit 20, 2006-11-01 Customer Letter – 3MBH00008941.
[60] Exhibit 23, 2009-06-04 Ion Armor Testing Report – 3MBH00025006.
[61] *Id.* (emphasis added).
[62] *Id.*

Following these tests, the Project Ducky team concluded that the new prototype with a HEPA filter and antimicrobial protection was "achievable from an operations and technical standpoint."[63] While the team recognized that the prototype would "provide significant gains" regarding "the actual assurance of cleanliness in the Bair Hugger product,"[64] neither the antimicrobial coating nor HEPA filtration were implemented in the product. The decision to terminate the project in deliberate disregard of patient safety was made shortly before the company entered into acquisition negotiations, even though it could have added antimicrobial coating to the device for just under two dollars per unit. [65]

Possible design changes began anew after acquisition. In 2013, company executives discussed a peer-reviewed study documenting the reduced filtration of the Bair Hugger. Clinical Director Al Van Duren proclaimed that "the change to new filter material was dictated by engineering concerns prior to the widespread appreciation of the importance of particulates discharged by the warming unit."[66] In response, the company's Chief Medical Director, Dr. Michelle Hulse-Stevens, declared that the device "does not have a filtration efficiency that adequately mitigates particulates in the air coming out after filtration."[67]

Attempts to solve the filtration and internal contamination issue soon followed. In late 2013, R&D Manager Glen Maharaj wrote to a group of company executives regarding customer queries on filtration. He stated that "[a]ll we can do is stick by our claim/statement

[63] Exhibit 21, 2009-05-20 PowerPoint Presentation – 3MBH00022625.
[64] *Id.*
[65] *Id.*
[66] Exhibit 24, 2013-08-24 Internal Memorandum – 3MBH01617179–80.
[67] *Id.*

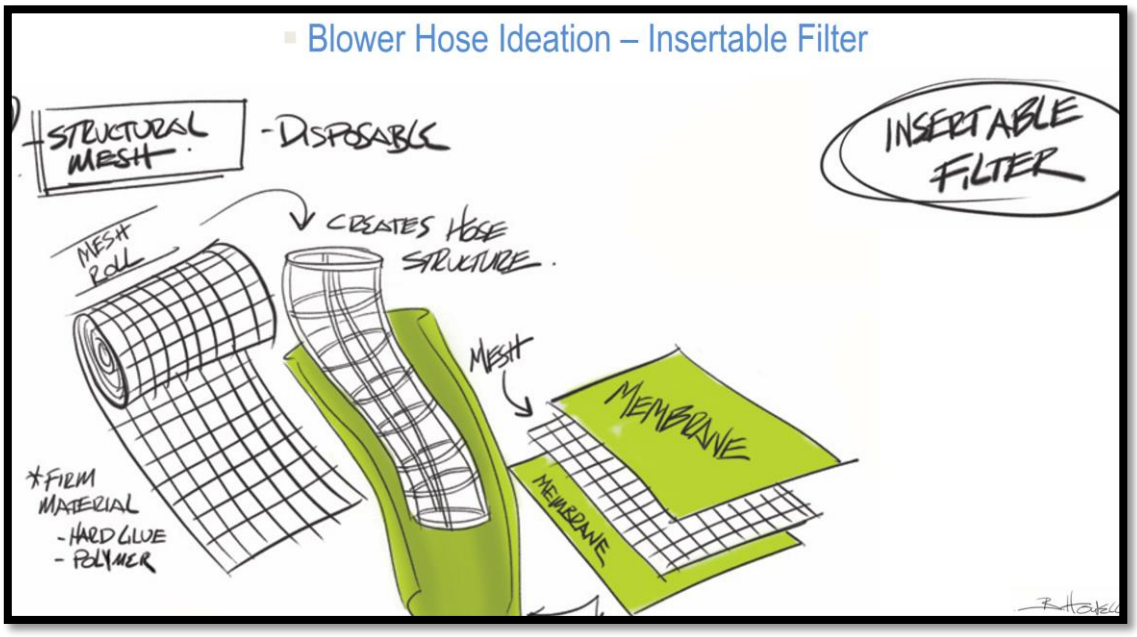
of 'high efficiency.'"[68] He also stated that the company was once again in the "process of looking to improve [the] filter."[69] In conscious disregard of patient safety, no changes were made to the Bair Hugger. Rather, the company's Marketing Manager admitted "[o]ne of the reasons why we've elected to use the filter we do is because of its cost structure."[70]

At the same time, Technical Manager Craig Oster voiced concern about a peer-reviewed study finding that the Bair Hugger harbored dangerous pathogens. Suspecting that "bacterial growth may occur between uses," he suggested "putting an antimicrobial coating on the inside of [the] Bair Hugger."[71] He also recommended "a very inexpensive antimicrobial coating on the inside of [the] blanket and gown tubes."[72] A Senior Research Specialist agreed with those solutions, affirming that "it is possible to coat all [the] suggested surfaces [of the device] with the quat antimicrobials and other chemistries."[73]

Although none of those recommendations were ever approved, Dr. Winston Tan attempted to develop a new hose design to solve the internal contamination issue. This project, known as the "Blower Hose Ideation" project, led to numerous concepts to combat bacterial growth in the hose of the Bair Hugger.[74] As noted by Plaintiffs' expert Dr. Yadin David, "it is apparent that 3M was acutely aware that the hose had significant cleanliness

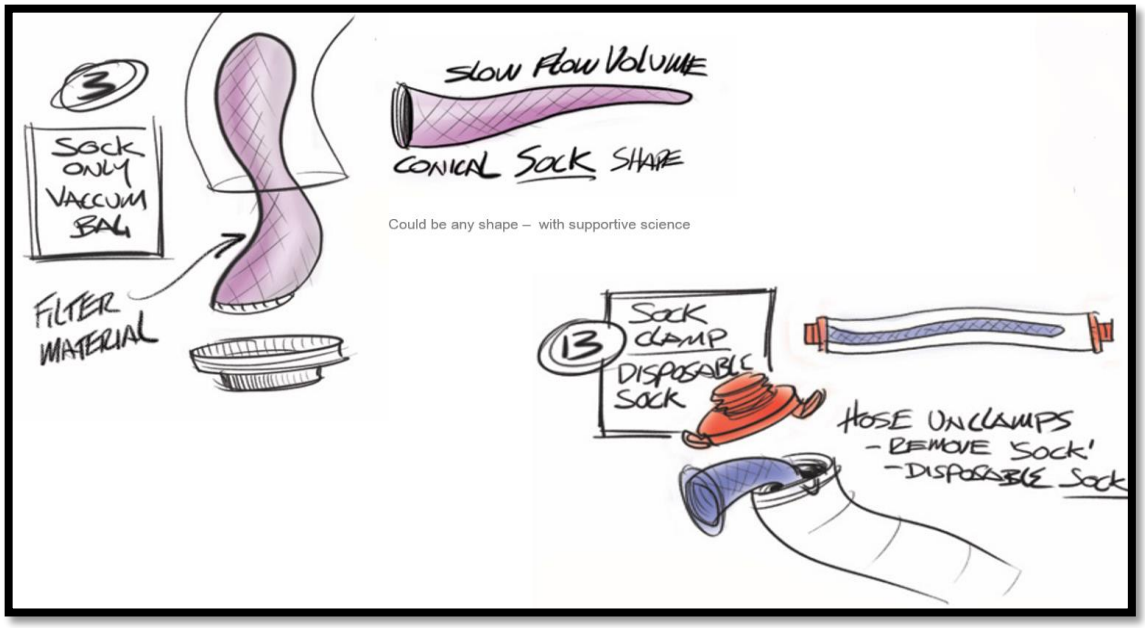
[68] Exhibit 15, 2013-10-07 Internal Email – 3MBH00126140.
[69] *Id.*
[70] Exhibit 25, Deposition of Mark Scott at 205:13–14.
[71] Exhibit 26, 2013-08-26 Internal Email – 3MBH00542396.
[72] *Id.*
[73] *Id.*
[74] Exhibit 27, 2014-03-05 Blower Hose Ideation PowerPoint – 3MBH00630074.

issues given the variety of design concepts seeking to address this problem."[75] For instance, Dr. Tan's team explored an insertable filter design for the hose end of the Bair Hugger:



[76]

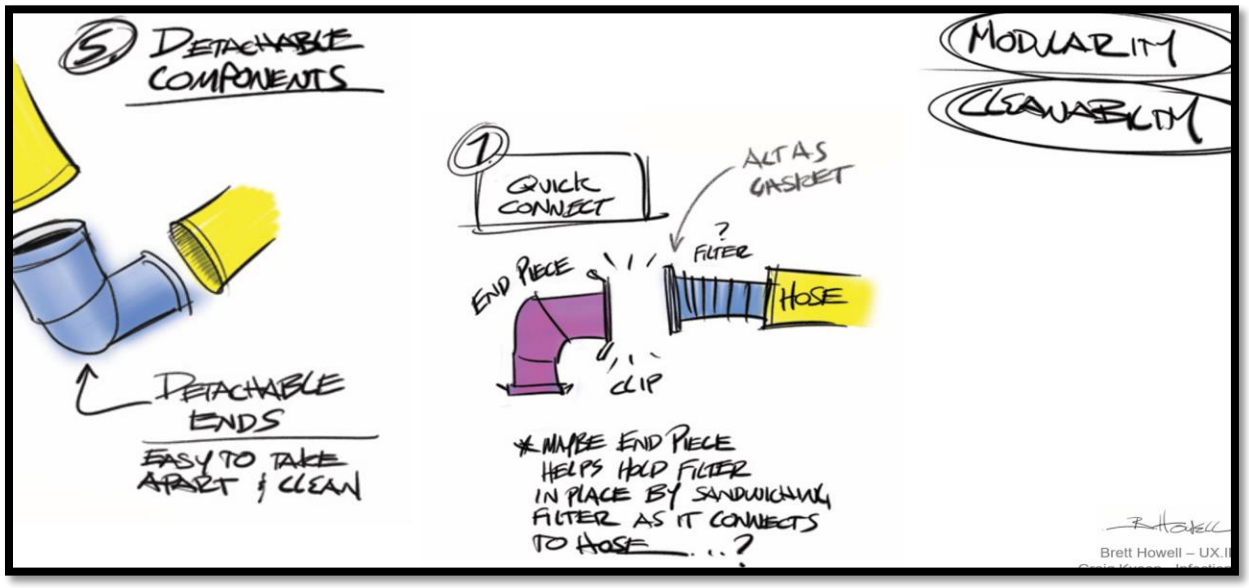
His team also developed concepts for a sock filter at the hose end of the unit:



[77]

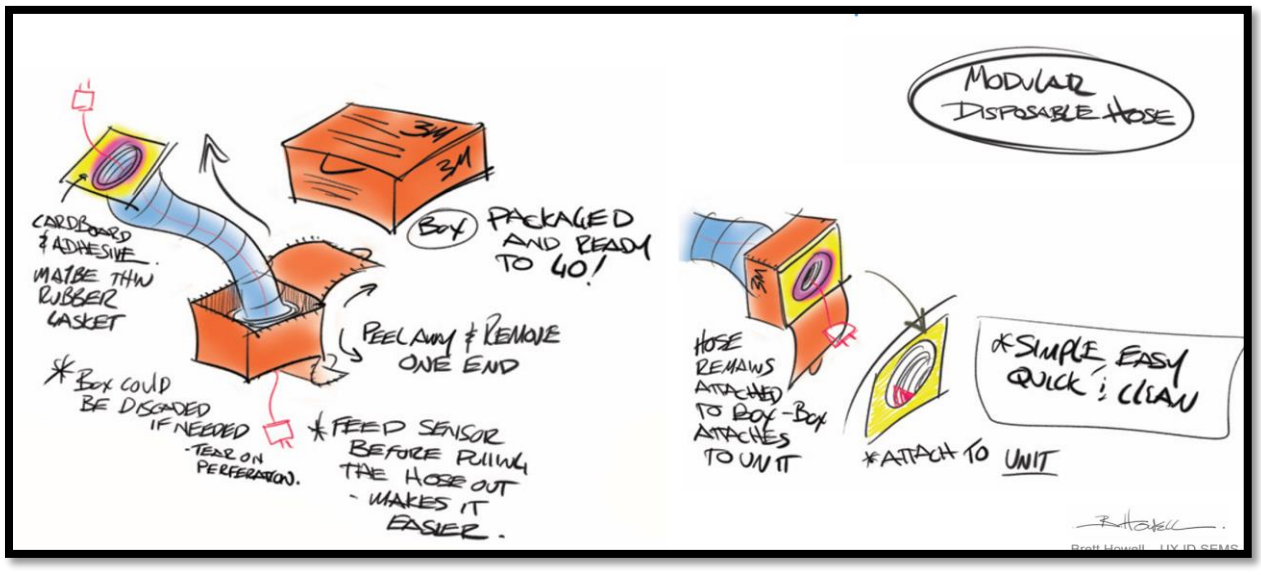
[75] Exhibit A, Report of Dr. Yadin David at 36.
[76] Exhibit 27, 2014-03-05 Blower Hose Ideation PowerPoint – 3MBH00630074.
[77] *Id.*

Dr. Tan's team then explored a design change to a modular hose design which could be disassembled. A modular hose could be cleaned and sterilized, unlike the current hose:



78

His team further developed a concept for a pre-packaged disposable hose, which would eliminate any possibility whatsoever of bacterial contamination inside of the hose:



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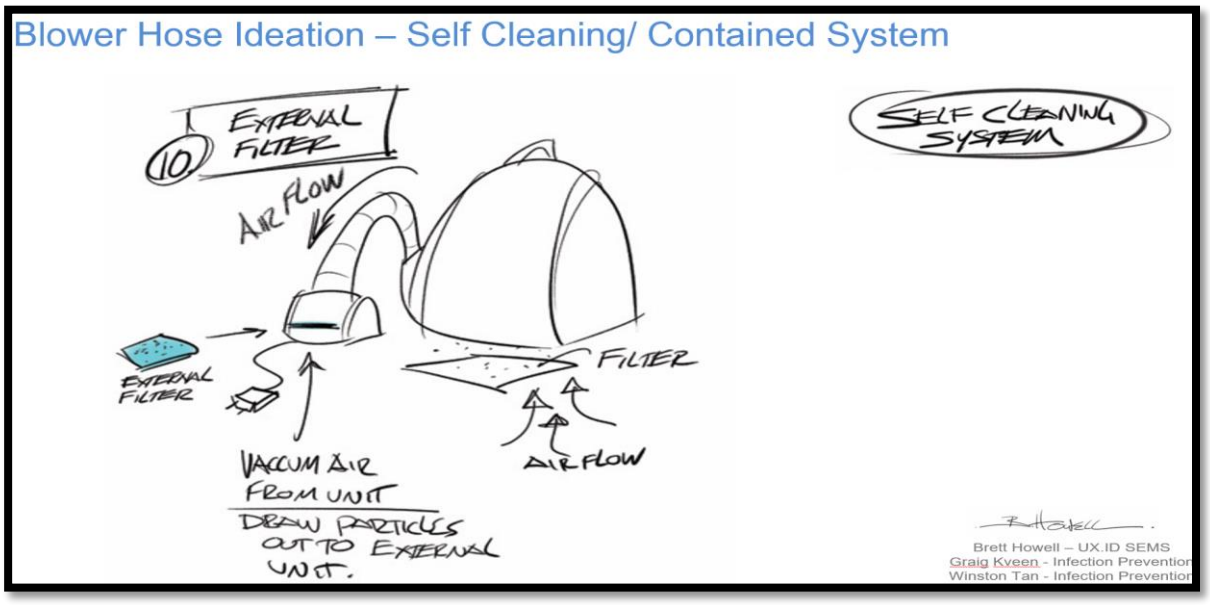
[78] *Id.*
[79] *Id.*

Finally, Dr. Tan's team even considered self-cleaning or self-contained systems:



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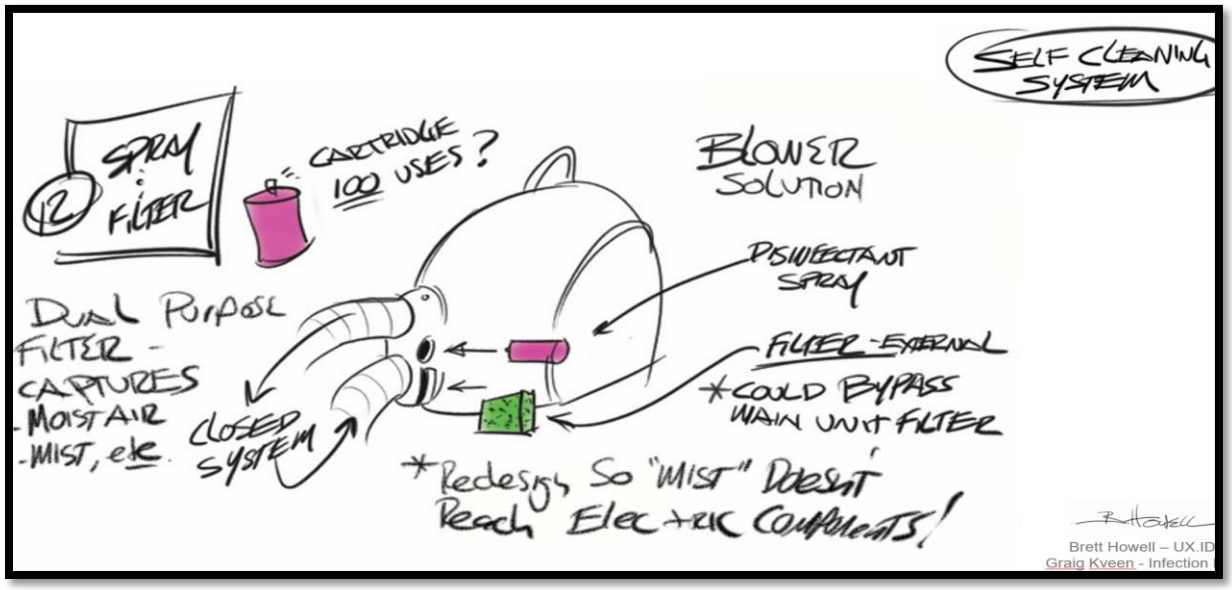
The concept for a self-cleaning system used internal disinfectants and a closed airflow system in which waste heat was recirculated through the Bair Hugger system:



81

[80] *Id.*
[81] *Id.*

Though Plaintiffs' expert Dr. Yadin David has explained that a self-cleaning, re-circulating design "would address both of the mechanisms of risk posed by the Bair Hugger – air circulation and internal contamination,"[82] Defendants deliberately chose not to implement any of these design changes. As a result, Dr. Tan began working on yet another filtration project in late 2015, attempting to develop "a design using HEPA grade media."[83] After months of investigation, however, Dr. Tan informed the filter supplier who he had been working with of a sudden "change in project scope" and that "[m]anagement would rather have us look into how we can take costs out of the current rectangular filter."[84]

To this day, not one of the foregoing design changes has been implemented in the Bair Hugger, even though all of those changes would have reduced, if not eliminated, the potential for internal contamination of the device. Since internal contamination of the Bair Hugger can cause contamination of the sterile surgical field,[85] which in turn increases the risk of deep joint infection in orthopedic patients,[86] Defendants' decision not to prevent internal contamination of the device "constitute[s] a *prima facie* case that [they] acted with deliberate or conscious disregard for the rights or safety of others." *In re Mirapex*, 2007 WL 9636345, at *9; *see In re Prempro Prods. Liab. Litig.*, 586 F.3d 547, 572 (8th Cir. 2009) (pattern of inaction in addressing safety risk constituted reckless disregard of safety).

[82] Exhibit A, Report of Dr. Yadin David at 38.
[83] Exhibit 28, 2015-07-16 Internal Email – 3MBH01922062.
[84] *Id.*
[85] *See* Exhibit B, Report of Dr. William Jarvis at 10–13.
[86] *See* Exhibit E, Report of Dr. Jonathan Samet at 13–17.

4. Defendants Know of Scientific Literature Finding Infection Risks.

Over the last ten years, Defendants have encountered numerous scientific studies identifying patient safety risks from use of the Bair Hugger in orthopedic surgeries. Any single one of the studies identified below would have caused a reasonably prudent manufacturer to seriously investigate the issue, particularly among orthopedic patients.[87] *See, e.g.*, *In re Levaquin*, 2010 WL 7852346, at *10 ("From [plaintiffs'] evidence . . . a jury could reasonable infer that defendants . . . had knowledge of or intentionally disregarded medical research regarding Levaquin's tendency to cause tendon injuries, particularly in seniors using corticosteroids[.]"). Despite their knowledge of these studies, Defendants admit that no responsive study or investigation was ever done.[88] *See In re Mirapex*, 2007 WL 9636345, at *9 (granting motion to add claim for punitive damages in part because "numerous reports of compulsive gambling from the clinical trials should have induced [defendants] to research the issue further and to warn patients about the possible side effects"). Defendants therefore deliberately disregarded patient safety. *See In re Prempro*, 586 F.3d at 572 (concluding that pattern of undermining "adverse" studies demonstrated a reckless disregard of patient safety sufficient to allege punitive damages).

For example, as early as 2009, Defendants reviewed a scientific study published in ORTHOPEDIC REVIEWS entitled *Forced air warming: a source of airborne contamination*

[87] *See, e.g.*, Exhibit B, Report of Dr. William Jarvis at 16 ("It has been estimated that rather than large numbers of micro-organisms required to cause many infections, that as few as 1-10 CFUs [colony forming units] are required to cause a [periprosthetic joint infection].").
[88] *See, e.g.*, Exhibit 5, Deposition of Corporate Representative Al Van Duren at 258:5–13; 314:21-315:3.

in the operating room?[89] The authors of the study not only discovered that the internal surfaces of Bair Hugger blowers were contaminated with pathogens,[90] but the findings revealed that Bair Hugger blowers emit a multitude of particles into the surgical field.[91] An article published one year later in the AMERICAN JOURNAL OF INFECTION CONTROL, entitled *Forced-air warming blowers: an evaluation of filtration adequacy and airborne contamination emissions in the operating room*, corroborated those findings.[92] Although internal contamination of the Bair Hugger may increase the dose of bacteria exiting the device,[93] Defendants did nothing to investigate the safety issue; instead, they "undertook misleading public relations campaigns, asserting that there was no relationship between [infections] and [internal contamination]."[94] *See In re Mirapex*, 2007 WL 9636345, at *1.

Along with research showing internal contamination of the device, Defendants were aware of scientific evidence documenting another mechanism by which the Bair Hugger delivered bacteria to the surgical site—disruption of operating room airflow. In 2011, McGovern et al. published an article entitled *Forced-air warming and ultra clean*

[89] Exhibit 29, M. Albrecht, et al. *Forced air warming: a source of airborne contamination in the operating room?* ORTHOPEDIC REVIEWS (October 2009).
[90] *Id.*
[91] *Id.*
[92] Exhibit 30, M. Albrecht, et al. *Forced-air warming blowers: an evaluation of filtration adequacy and airborne contamination emissions in the operating room*. AMERICAN JOURNAL OF INFECTION CONTROL (November 2010).
[93] Exhibit E, Report of Dr. Jonathan Samet at 16.
[94] *See* Exhibit 31, Response Communication Plan – 3MBH00031537–56; *see also* Exhibit 32, Deposition of Troy Bergstrom at 93:20-94:1.

ventilation do not mix in the renowned JOURNAL OF BONE AND JOINT SURGERY.[95] The authors tested neutrally buoyant bubbles in a simulated orthopedic operation and found that heated exhaust from the Bair Hugger mobilizes unsterile air from the floor of the operating room to the surgical site.[96] The authors also compared infection rates during two periods: one with the Bair Hugger in use and one with air-free warming in use.[97] The authors identified a statistically significant risk ratio of 3.8 when the Bair Hugger was in use versus the air-free warming period. The Bair Hugger thereby increased the infection risk by 3.8.[98]

According to Plaintiffs' expert Dr. Jonathan Samet, an epidemiologist specializing in airborne particulate exposure, the McGovern study "documents a statistically significant association unlikely to be explained by confounding or other bias."[99] In other words, **based on the elevated 3.8 risk ratio reported in the study, "the Bair Hugger device would constitute a substantial contributing cause" to infections in orthopedic patients**.[100] Defendants, however, publically derogated the study instead of investigating its merits. *See In re Levaquin*, 2010 WL 7852346, at *10 (disregarding peer-reviewed research on safety issue constitutes *prima facie* proof that defendant deliberately disregarded patient safety).

As more and more research revealed the patient safety risks of using the Bair Hugger in orthopedic surgeries, Defendants continued to deliberately disregard the truth. Based on

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[95] Exhibit 32, P.D. McGovern, et al. *Forced-air warming and ultra clean ventilation do not mix.* THE JOURNAL OF BONE AND JOINT SURGERY (November 2011).
[96] *Id.*
[97] *Id.*
[98] *Id.*
[99] Exhibit E, Report of Dr. Jonathan Samet at 16.
[100] *Id.* at 17 (emphasis added).

increased temperatures and particle counts over the surgical site, two peer-reviewed studies published in 2011 found that the Bair Hugger disrupts operating room airflow and thereby causes nonsterile air to enter the sterile surgical field.[101] The same held true in 2012, as Defendants reviewed a scientific study published in the JOURNAL OF BONE AND JOINT SURGERY entitled *Forced-air patient warming blankets disrupt unidirectional airflow*[102] and another study published in ANESTHESIA & ANALGESIA entitled *Patient Warming Excess Heat: The Effects of Orthopedic Operating Room Ventilation Performance*.[103] Both studies used neutrally buoyant bubbles to track whether excess heat from the Bair Hugger mobilized bubbles and thus particles to the surgical site. In both studies, the authors found that the Bair Hugger significantly disrupted operating room airflow near the surgical site.[104]

If those studies were not enough to demonstrate the safety risks of using the Bair Hugger in orthopedic surgeries, Defendants also reviewed a 2013 study published in the AMERICAN ASSOCIATION OF NURSE ANESTHETISTS JOURNAL entitled *Forced-air warming design: evaluation of intake filtration, internal microbial buildup, and airborne*

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[101] *See* Exhibit 34, A.J. Legg, et al. *Do forced air patient warming devices disrupt unidirectional downward airflow?* THE JOURNAL OF BONE AND JOINT SURGERY (February 2012); *see also* Exhibit 35, K.B. Dasari, et al. *Effect of forced air warming on the performance of operating theatre laminar flow ventilation.* ANAESTHESIA (March 2012).
[102] Exhibit 36, A.J. Legg, et al. *Forced-air patient warming blankets disrupt unidirectional airflow.* THE JOURNAL OF BONE AND JOINT SURGERY (March 2013).
[103] Exhibit 37, K. Belani, et al. *Patient Warming Excess Heat: The Effects of Orthopedic Operating Room Ventilation Performance*. ANESTHESIA & ANALGESIA (August 2013).
[104] *Id.*

contamination emissions.[105] The authors evaluated the intake filtration efficiency of a Bair Hugger 750 filter and found it was only 63.8% efficient.[106] The authors also performed laboratory testing which found that 100% of Bair Huggers were contaminated with pathogenic growth.[107] Particle counting further showed that 96% of Bair Huggers were emitting significant levels of internally generated airborne contaminants out of the hose.[108] Though the researchers recommended using HEPA filtration or redesigning the device to allow for internal cleaning,[109] Defendants ignored these recommendations even in the face of subsequent literature recommending the use of alternative patient-warming devices.[110]

All these studies provide substantial evidence of the safety risk of the Bair Hugger. Plaintiffs' expert Dr. William Jarvis, who "worked in various leadership roles at the CDC in Atlanta, Georgia, focusing on the investigation and prevention of infectious diseases," has concluded that the scientific literature includes "substantial evidence of the patient safety risk posed by the Bair Hugger."[111] The computational fluid dynamics modeling conducted by Plaintiffs' expert Dr. Said Elghobashi, along with the epidemiological

[105] Exhibit 38, M. Reed, et al. *Forced-air warming design: evaluation of intake filtration, internal microbial buildup, and airborne contamination emissions.* AANA JOURNAL (August 2013).
[106] *Id.*
[107] *Id.*
[108] *Id.*
[109] *Id.*
[110] Exhibit 39, A.M. Wood, *Infection control hazards associated with the use of forced air warming in operating theatres*. JOURNAL OF HOSPITAL INFECTION (November 2014).
[111] Exhibit B, Report of Dr. William Jarvis at 1, 12.

findings in Dr. Samet's report, prove as much.[112] From the great weight of the literature, Defendants should have understood that the Bair Hugger has "inadequate air filtration efficiency, internal bacterial contamination (including intake and exhaust hoses), exhaust[s] microbial contaminants, interfere[s] with OR airflow (directional or non-directional), and can introduce particles/microbial contaminants into the surgical 'sterile' field."[113] After all, Defendants knew "the Bair Hugger device causally increases risk for deep joint infection,"[114] as duly recognized by Corporate Representative Al Van Duren.[115]

Because Defendants' inaction in the face of these scientific studies demonstrates an intentional disregard for patient safety, Plaintiffs should be allowed to allege a claim for punitive damages. *See In re Prempro*, 586 F.3d at 572 (finding sufficient evidence to award punitive damages because a "jury could find that although each study added to the evidence suggesting a risk of [injury from use of the product], [the defendant] nevertheless continued to engage in a practice of both inaction and mitigation"); *In re Mirapex*, 2007 WL 9636345, at *9 (failure to conduct research despite "numerous reports" demonstrating negative side effect of drug provided *prima facie* evidence for plaintiffs to assert punitive damages claim); *cf. In re Levaquin*, 2010 WL 7852346, at *11 ("Defendants further attempt to invalidate studies cited by [plaintiff] as methodologically flawed . . . should not preclude [him] from asserting a punitive damages claim.") (citing *In re Prempro*, 586 F.3d at 573).

[112] *See* Exhibit D, Report of Dr. Said Elghobashi; *see also* Exhibit E, Report of Dr. Jonathan Samet at 9–17.
[113] Exhibit B, Report of Dr. William Jarvis at 8.
[114] Exhibit E, Report of Dr. Jonathan Samet at 16.
[115] Exhibit 40, Internal Document with Al Van Duren Comments – 3MBH00001336.

5. Defendants Know the Literature They Cite Has Significant Limits.

For over two decades, Defendants have cited three studies to support the safety of using the Bair Hugger in orthopedic surgeries. First, the company relies on a 1993 study by Zink and Iaizzo entitled *Convective warming therapy does not increase the risk of wound contamination in the operating room*. This study was sponsored by Dr. Scott Augustine during the development of the obsolete Bair Hugger 500 series.[116] The experiment involved eight volunteer subjects on simulated surgical tables with petri dishes on their abdomen.[117] The test was conducted with new and uncontaminated units, all of which used the higher-efficiency M10 filter compared to current units.[118] There were no surgeons, staff, equipment, or any flow obstructions in the room.[119] Even under these favorable conditions, bacterial contamination was detected on many of the culture plates.[120]

The company also relies on a study by Huang et al. entitled *The Bair Hugger patient warming system in prolonged vascular surgery: an infection risk?* This study was also conducted with the Model 500 series units which had higher efficiency filters and lower airflow compared to current units.[121] The study involved 16 patients in vascular surgeries, not orthopedics.[122] Moreover, the study was not controlled, as the Defendants' clinical

[116] Exhibit 5, Deposition of Corporate Representative Al Van Duren at 283:1.
[117] Exhibit B, Report of Dr. William Jarvis at 13.
[118] *Id.*
[119] *Id.*
[120] *Id.*
[121] Exhibit 5, Deposition of Corporate Representative Al Van Duren at 213:8.
[122] *Id.* at 217:9–10.

consultant warned in a 2010 email.[123] Though Huang et al. found less bacteria at the end of the surgery when the Bair Hugger was turned on compared to the start of the surgery when it was turned off, the authors admit that "the higher count at the beginning of surgery . . . may be due to the unrestricted movement of personnel in and out of the operating room, with opening and closing of doors, leading to increased air flow and turbulence."[124]

Finally, Defendants point to a 2009 study by Moretti et al. entitled *Active warming systems to maintain perioperative normothermia in hip replacement surgery: a therapeutic aid or a vector of infection?* As a threshold matter, the authors admit the "sample size of patients was small for the calculation of the statistically incidence of surgical site infection after the use of the Bair Hugger."[125] The study also used the European Model 505E, which Defendants' Corporate Representative admits has a lower airflow than the domestic Model 505, which itself has far lower airflow compared to the Model 750.[126] Furthermore, Defendants' clinical consultant Dr. Sessler warned that the study was not randomized,[127] while the authors of the study expressly recognized that "further studies are needed."[128]

Despite Defendants' assertions over the last two decades,[129] these underpowered and "limited" studies do not prove let alone demonstrate "the safety of the Bair Hugger."[130]

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[123] Exhibit 41, 2010-09-23 Internal Email – 3MBH01223897.
[124] Exhibit 5, Deposition of Corporate Representative Al Van Duren at 217:16–21.
[125] Exhibit 42, 2009-07-31 Moretti Study – 3MBH00001377.
[126] Exhibit 5, Deposition of Corporate Representative Al Van Duren at 213:3–12.
[127] *Id.*
[128] Exhibit B, Report of Dr. William Jarvis at 13.
[129] *See, e.g.*, Exhibit 43, 2011-03 3M Article – 3MBH00044027–28.
[130] Exhibit E, Report of Dr. Jonathan Samet at 12–13.

Although Defendants' Corporate Representative acknowledged many of the methodological limitations of the foregoing studies, the company never "publicized these limitations" to its customers.[131] When the company's Chief Medical Director attended the Internal Consensus Meeting on the Prevention of Joint Infections in 2013, she learned of "amazing concern about any particulates in the air during joint replacement surgery and almost uniform comment that FAW [forced-air warming] increases particulates in air."[132] Defendants' Corporate Representative even admitted that "[b]ased on the data that we have today, including the study funded by 3M as well as other studies, **every single study indicates that the Bair Hugger increases the particle count over the sterile field**."[133]

Although Defendants understood that particles are a proxy for bacteria,[134] the company touted these fatally flawed studies to customers and thereby continued to misrepresent the safety of the Bair Hugger.[135] This evidence alone, "if unrebutted, could be relied upon at trial to find that [Defendants deliberately] disregarded the high probability of injury to the rights or safety of others." *E.g.*, *In re Mirapex*, 2007 WL 9636345, at *9.

6. Defendants Manipulated Scientific Research for Commercial Gain.

In January 2010, Sales Manager Suzanne Tullis received a forwarded email from a member of the Surgical Care Improvement Project.[136] The message stated that several

[131] Exhibit 5, Deposition of Corporate Representative Al Van Duren at 291:3–9.
[132] Exhibit 44, 2013-08-03 Internal Email – 3MBH00580475.
[133] Exhibit 5, Deposition of Corporate Representative Al Van Duren at 258:5–10 (emphasis added).
[134] Exhibit 45, 2010-03-01 Internal Email – 3MBH00050770–71.
[135] *See* Exhibit 46, 2011-03 3M Article – 3MBH00044027–28.
[136] Exhibit 47, 2010-01-21 Internal Email – 3MBH00024733.

"orthopedic physicians [had been] refusing the use of forced air warming devices for joint replacement procedures" because the devices "contribute to post-op wound infections [as a result] of circulating air."[137] The email further stated that the "literature they have and what I have found seems to support their position" as to the risk of deep joint infection.[138]

These kinds of emails became increasingly common given the growing volume of research from different sources which all pointed to the safety risks of Bair Hugger warming. In fact, Ms. Tullis informed various marketing executives that the "issue [was] everywhere," and she cried out for "a better strategy besides the Zink article."[139] The company therefore constructed and oversaw an experiment that it knew would produce favorable results. It did so by having company executives design and oversee the experiment. It then solicited longtime paid consultants to sign on as authors even though they lacked the expertise to review or confirm any of the technical details of the experiment.

The underlying testing that was the subject of the published paper was overseen by Al Van Duren and Gary Hansen, Defendants' Directors of Clinical Affairs and Research and Development, respectively. The two executives travelled all the way to the Netherlands just to conduct the experiment.[140] Mr. Van Duren and Mr. Hansen created the testing design and protocol, which involved a particle test to visualize operating room airflow, and they brought their own testing equipment.[141] Predictably, Mr. Hansen and Mr. Van Duren

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[137] *Id.*
[138] *Id.*
[139] *Id.*
[140] Exhibit 48, 2010-01-17 Internal Email – 3MBH00001557.
[141] Exhibit 49, 2010-01-26 Internal Email – 3MBH00050756.

obtained data that was contrary to numerous published experiments, all of which had found a disturbance of the sterile surgical field as a result of the Bair Hugger. In this unusual test, a Bair Hugger underbody blanket was turned on for only five minutes, after which particles were counted near a simulated surgical site.[142] Even under this specious design, the raw data from the first testing location showed a "five-to-ten" fold increase in particle counts caused by the Bair Hugger in merely five minutes.[143] Hoping to avoid similar results, the company executives changed locations to conduct another test, although they recognized that the extremely small sample size prohibited the potential for more negative results.[144]

Company executive Gary Hansen drafted the paper on the testing.[145] During the drafting process, **the company decided "to delete from the transcript that there had been significantly higher counts seen with the underbody blanket at the Amersfoort hospital."**[146] It then recruited paid clinical consultants to attach their names to the data. In one such attempt, Defendants' Vice President acknowledged that the study was "part of a legal strategy which we have been carefully outlining."[147] Nonetheless, two paid consultants, Dr. Daniel Sessler and Mr. Russel Olmstead, signed on as authors, but neither one was qualified to validate the data. In 2011 email, Dr. Sessler asked Mr. Hansen: "If you haven't already, can you check the engineering details? Russ [Olmstead] probably

[142] Exhibit 16, Deposition of Dr. Daniel Sessler at 53.
[143] Exhibit 79, 2010-11-16 Internal Email – 3MBH00050932–33.
[144] Exhibit 50, 2010-10-20 Internal Email – 3MBH01223923.
[145] Exhibit 16, Deposition of Dr. Daniel Sessler at 66:24–67:1.
[146] *Id*. at 68 (emphasis added).
[147] Exhibit 51, 2010-04-23 Internal Email – 3MBH00024809.

doesn't know enough to confirm that they are all correct (and I certainly don't)."[148] Moreover, given the methodological problems with the paper, Dr. Sessler wrote Mr. Hansen an email titled "URGENT!!!!" in which he stated that "[w]e have a problem, in the form of an official complaint."[149] Dr. Sessler advised the company that the editor of the journal "want[ed] to discuss the issue[s] [with the paper] . . . [but] [u]nfortunately this topic [was] well outside [his] area of expertise so [he would] need [the company's] help."[150] He then declared that he was "pretty unhappy" because he "took this project on as a favor."[151]

Dr. Sessler had already proven to the company that he was more than willing to collaborate with the company so as to guarantee commercially favorable outcomes. As one example, when conducting earlier testing on the Bair Hugger underbody blanket, Dr. Sessler readily agreed to the company's curious request that he "not submit this paper for publication until we have had time to study it further."[152] Dr. Sessler responded as follows:

> Understood! We regard this as a collaborative effort to put the best face on a disappointing clinical result. Rather than a "response," **you can make suggestions and necessary changes right in the text of the manuscript**.[153]

In response to that message, company executives noted that Dr. Sessler was "actually giving [them] permission to word-smith his text."[154] Company employees were

[148] Exhibit 52, 2011-08-31 Internal Email – 3MBH01224622.
[149] Exhibit 53, 2012-08-31 Internal Email – 3MBH00130429.
[150] *Id.*
[151] *Id.*
[152] Exhibit 54, 2007-01-24 Internal Email – 3MBH00083780.
[153] *Id.* (emphasis added).
[154] Exhibit 55, 2007-01-24 Internal Email – 3MBH01211442.

accordingly instructed to "go after the offending parts [of the manuscript] directly" and not to be "shy about major changes." In fact, they were expressly instructed to "have at it."[155]

Ironically, in this MDL, Defendants engaged in wide-ranging discovery including a series of international depositions with promises of revealing bad-faith collusion between its competitor and various researchers. All these promises turned out to be baseless, potentially defamatory allegations.[156] Instead, it is Defendants who have a history of manipulating studies, colluding with researchers, and employing scare-tactics to convince scientists not to publish adverse research.[157] This approach to research reveals Defendants' commitment to commercial goals rather than public safety. Though willing to engineer what was essentially a commercial advertisement for the Bair Hugger under the guise of actual science, Defendants failed to perform any real testing on the issue of contamination. *See In re Levaquin*, 2010 WL 7852346, at *10–12 (defendants' attempt to "manipulate[] the Ingenix Study to produce a commercially favorable result" constituted *prima facie* evidence that "would provide a jury a basis for punitive damages under Minnesota law").

7. Defendants Repeatedly Refused to Conduct a Contamination Study.

Because Defendants "could neither prove nor disprove the fact that the Bair Hugger causes surgical-site infections,"[158] their clinical consultants repeatedly urged company executives to find the answer to the infection question, but they were rebuked at every turn.

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[155] *Id.*
[156] *See, e.g.*, Exhibit 56, Deposition of Paul McGovern at 458:1–5.
[157] *See, e.g.*, Exhibit 57, 2010-12-09 Internal Email – 3MBH00051040.
[158] Exhibit 58, Deposition of John Rock at 217:17.

In December 2010, Defendants' expert consultant Dr. Daniel Sessler recommended conducting a contamination study, stating, "I still recommend that you do a study with bacterial sampling during laminar flow surgery."[159] He raised the same issue again in March[160] and July 2011,[161] but the study never moved ahead.[162] Dr. Sessler told Defendants that refusing to do the study "seem[ed] like a dangerous strategy,"[163] to which company executives replied that they would "be meeting shortly to get [their] clinical priorities in order."[164] Ultimately, however, the company's Medical Director said the decision hinged on whether "core stakeholders" perceived such a study to be a "value added" activity.[165]

After another clinical consultant recommended that the company perform an outcome study "using aerobiology and consequent follow-up of patients undergoing [total joint arthroplasty] in a laminar flow room,"[166] Defendants consciously disregarded the advice of its clinical consultants by once again refusing to conduct such a dispositive study.

When Dr. Daniel Sessler was shot down again in August 2012, he declared that he was "pretty unhappy" with the company's decisions regarding scientific testing.[167] He stated the company's missteps were "completely preventable,"[168] and he lamented the fact

[159] Exhibit 59, 2010-12-27 Internal Email – 3MBH00051252.
[160] Exhibit 60, 2011-03-17 Internal Email – 3MBH00575107.
[161] Exhibit 61, 2011-07-15 Internal Email – 3MBH00575251.
[162] *Id.*
[163] Exhibit 62, 2011-11-28 Internal Email – 3MBH00132501.
[164] *Id.*
[165] Exhibit 63, 2012-03-13 Internal Email – 3MBH01619270.
[166] Exhibit 64, 2010-01-06 Internal Email – 3MBH00555876.
[167] Exhibit 53, 2012-08-31 Internal Email – 3MBH00130429.
[168] *Id.*

that if Defendants had conducted the appropriate testing the company would have "the full and complete answer to [the infection question]."[169] **Defendants' decision not to conduct scientific testing "was just short-sighted; there is no way to put any gloss on that."**[170]

Then again in March 2013, Dr. Sessler informed Defendants of the increasing volume of literature regarding the safety risks of Bair Hugger warming. Dr. Sessler advised Defendants that "[t]alking points won't resolve the issue or (much) limit the damage."[171] He therefore recommended a bacteriology study to "put this issue to bed,"[172] even though Clinical Director Al Van Duren still "strongly resisted conducting a study of this type."[173]

Despite ongoing offers from other notable scientists to conduct a contamination study on the company's behalf,[174] 3M's Clinical Research Manager stated that "decisions were made previously (at a high level) not to pursue clinical research on this topic."[175] 3M's Medical Director, Dr. Michelle Hulse-Stevens, further testified about the decision:

> Q. Now the "legal situation" was what, the lawsuits brought alleging that the Bair Hugger causes surgical-site infections?
>
> A. Correct. Yeah.
>
> Q. Okay. And by whom were you told that that decision had been made?

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[169] *Id.*
[170] *Id.* (emphasis added).
[171] Exhibit 65, 2013-03-20 Internal Email – 3MBH00134035.
[172] *Id.*
[173] Exhibit 66, 2013-04-04 Internal Email – 3MBH00107719.
[174] Exhibit 67, 2015-07-15 Internal Email – 3MBH01330587.
[175] *Id.*

A. Oh boy. I don't remember. I just – I remember discussions about doing the study just stopped after we had this input from our legal team.

Q. Okay. Now the Harper study will not answer this question; will it?

A. No.[176]

…

Q. Mr. Van Duren states, "Prospective clinical studies designed to show increases in SSI rates are notoriously difficult to conduct in part because of the large sample sizes needed to provide adequate power;" correct?

A. Yes.

Q. Okay. "Are there other types of studies that you believe provide adequate evidence for the adoption of particular interventions which could be less difficult to conduct?" Do you see that?

A. Yes.

Q. And one of them would be an aerobiology study; correct?

A. That's a possibility, yes.

Q. That's the one that hasn't been conducted; correct?

A. We have not conducted that study.

Q. And decisions have been made at the highest levels not to conduct it; correct?

A. Yes.[177]

[176] Exhibit 68, Deposition of Michelle Hulse-Stevens at 258:20–259:12.
[177] *Id.* at 292:7-293:4 (emphasis added).

At bottom, company executives were deeply worried about the prospect of an aerobiology study. During a strategy meeting known as "War Games," company executives discussed various "nightmare" scenarios that would threaten the profitability of the Bair Hugger in the marketplace.[178] **One of those nightmares involved "someone [conducting] a real study on FAW [forced-air warming] and contamination."**[179] Defendants feared a "definitive study showing FAW as a source of SSI [surgical site infections]," as well as the potential prospect of a mass "recall of [Bair Hugger] units for contamination issues."[180]

Upon reviewing the record of Defendants' conduct, Plaintiffs' expert Dr. Yadin David concluded that "Defendant[s] failed to follow common practices in the medical device manufacturing industry by failing to adequately investigate the issue of the Bair Hugger's impact on orthopedic implant surgeries," thereby showing a "reckless disregard for patient safety." [181] Indeed, based on strikingly similar evidence of corporate efforts to avoid unfavorable research, Judge Noel reached a similar conclusion in the Mirapex MDL. *See In re Mirapex*, 2007 WL 9636345, at *8 (allowing plaintiffs to amend complaint to assert punitive damages claim in part because "expert consultants recommended that a study should be conducted" on side effects but defendant continually "delayed conducting [the] study"); *see also In re Prempro*, 586 F.3d at 572 (declaring that continual "failure to organize one study to allow for adequate evaluation" of side effects associated with the product would constitute *prima facie* evidence of the reckless disregard for patient safety).

[178] Exhibit 69, 2011-03-17 "War Games" Notes – 3MBH00053467.
[179] *Id.* (emphasis added).
[180] *Id.*
[181] Exhibit A, Report of Dr. Yadin David at 44.

8. Defendants Willfully Suppressed Potentially Harmful Testing.

In addition to refusing to conduct necessary testing, Defendants aggressively sought to prevent and discredit unfavorable testing of the Bair Hugger. Defendants' Director of Marketing Communications admitted that he was instructed to create materials intended to undermine any study that found the Bair Hugger posed a patient safety risk.[182] In fact, he "drafted talking points" on each of the studies discussed in Section 4, *supra*, all of which Defendants argued were "misinformation."[183] Any unfavorable research was immediately rejected without consideration, attacking the authors' methods, motives, and *bona fides*.

For example, Defendants received notice in late 2008 that a study with results unfavorable to the Bair Hugger would be published within the week. Defendants' Director of Marketing subsequently told other company executives "[i]t seems we should have some talking points to address the findings."[184] Likewise, less than an hour after learning that physicians at Stanford Medical School had published a paper concerning contaminated Bair Hugger units, Mr. Hansen told his employees to make "a vigorous challenge to these findings."[185] Even when unfavorable information about the Bair Hugger's risk of contamination appeared in the OPERATING THEATRE JOURNAL in 2010, the company's Director of Marketing instructed fellow executives "to 'poke holes' in the statements."[186]

[182] Exhibit 32, Deposition of Troy Bergstrom at 65–71.
[183] *Id.* at 69:7.
[184] Exhibit 70, Deposition of Jana Stender at 88:5-88:13.
[185] Exhibit 71, 2009-09-02 Internal Email – 3MBH00024680.
[186] Exhibit 72, 2010-01-14 Internal Email – 3MBH00002792.

Defendants' tactics only escalated as time went on. In 2012, Defendants attempted to coerce the editor of the JOURNAL OF BONE AND JOINT SURGERY to retract an adverse study about the Bair Hugger. Bob Buehler, 3M's Vice President of the Patient Warming Business, urged the company to give the editor **"reasons why not retracting this would cause him pain."**[187] Then, in a lengthy memorandum entitled "Response Communication Plan," company executives outlined specific plans to discredit and undermine critical research.[188] Discussing plans to coerce one researcher, they concluded that "[Dr.] Leaper may not be motivated to change his stance unless he feels his good image could be tarnished."[189] Defendants also invoked the influence of its outside clinical consultants to put pressure on editors not to publish research unfavorable to the Bair Hugger. In one email, executives discussed an update from their paid consultant Dr. Daniel Sessler that an "OR Manager article will not be published" because "Dan spoke to the editor," so "it's dead."[190]

Along with suppressing harmful testing, Defendants prevented additional testing. Shortly after the 3M acquisition, Defendants' executives learned that upper management had committed the Bair Hugger and other products to a bundled infection study being performed by Professor Judith Tanner in the United Kingdom.[191] Numerous executives sought to remove the Bair Hugger from the study, but the company had "already

[187] Exhibit 73, 2012-08-01 Internal Email – 3MBH0125823 (emphasis added).
[188] Exhibit 32, Deposition of Troy Bergstrom at 171:6.
[189] Exhibit 73, Response Communication Plan – 3MBH00005744.
[190] Exhibit 57, 2010-12-09 Internal Email – 3MBH00051040.
[191] Exhibit 75, 2010-12-08 Internal Email – 3MBH00042660.

committed" the Bair Hugger to the study.[192] Nonetheless, after repeated discussions, the company withdrew from the study, while at the same time fearing whether one of its patient-warming competitors would "issue contamination kits to orthos around country."[193]

Defendants also steered independent organizations away from testing the Bair Hugger. For example, in 2008, prior to publishing its "buyers' guide," an independent evaluation organization called CEDAR conducted an inquiry of all "stakeholders" regarding forced-air warming devices. Defendants were adamant that "[w]e don't want them trying to do their own testing,"[194] so they avoided such testing. Likewise, Defendants learned that another independent organization (ECRI) sought to evaluate the safety risks of the Bair Hugger.[195] Yet Defendants immediately sought to limit the scope of ECRI's review of the Bair Hugger. In fact, company executive Gary Hansen even recommend that **"[o]ur first step with ECRI should be preventing them from doing their own testing."**[196]

In the *Prempo* litigation, the Eighth Circuit discussed how a pattern of undermining clinical research of a product can support a finding of deliberate disregard of public safety:

> The district court noted that the evidence showed that [defendant] attempted to convey that there was no definitive link between [Prempro] and breast cancer. But [plaintiffs'] claim also rested on the theory that [defendant] deliberately avoided studying [Prempo's] effect on breast cancer. Moreover, a jury could reasonably construe [defendant's] documents as repeated efforts over many years to undermine information and studies that attempted to show a breast cancer

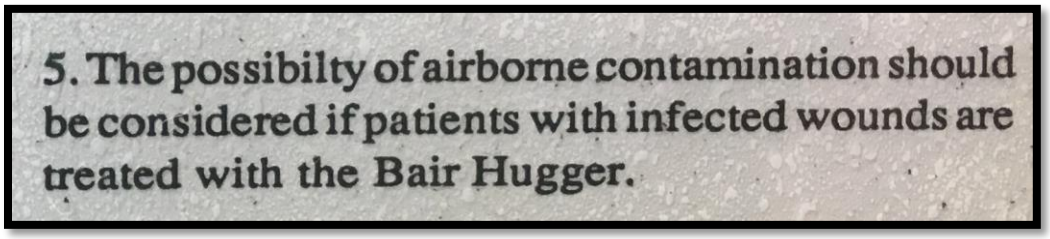
[192] *Id.*
[193] Exhibit 69, 2011-03-17 Internal Memorandum – 3MBH00053467.
[194] Exhibit 76, 2008-08-22 Internal Draft – 3MBH00108244.
[195] The Emergency Care Research Institute is a private think-tank that reviews health care technology.
[196] Exhibit 77, 2011-02-07 Internal Email – 3MBH00544754 (emphasis added).

> link. A jury reasonably could find that these efforts allowed [defendant] to promote the false understanding that [Prempo] was not linked to breast cancer and then to promote reliance on this understanding.

In re Prempro, 586 F.3d at 572. Here, too, Defendants not only avoided conducting proper studies, but they attacked all information showing the Bair Hugger posed an infection risk. Plaintiffs have thus raised more than enough evidence to allege a punitive damages claim. *In re Levaquin*, 2010 WL 7852346, at *10 (allowing addition of punitive damages claim since defendants prevented action that would "negatively impact the drug's reputation").

9. Defendants Deliberately Failed to Warn of a Known Safety Risk.

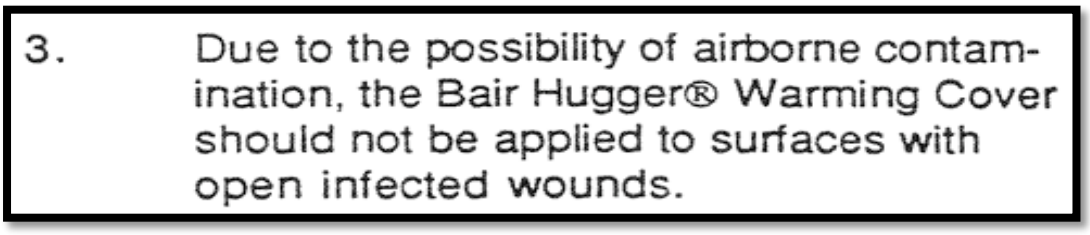
Defendants also deliberately failed to warn consumers of the risks of airborne contamination. It is undisputed that Defendants provided no warnings for the Bair Hugger Models 505, 750, or 775 regarding the potential for airborne contamination.[197] Defendants' **Corporate Representative admitted these warnings were omitted "despite the fact that the risk of airborne contamination was in fact known to the company at that time."**[198] Indeed, the Bair Hugger Model 200, which was not intended for use in operating rooms, included a warning as to the potential for airborne contamination.[199] It cautioned:



[200]

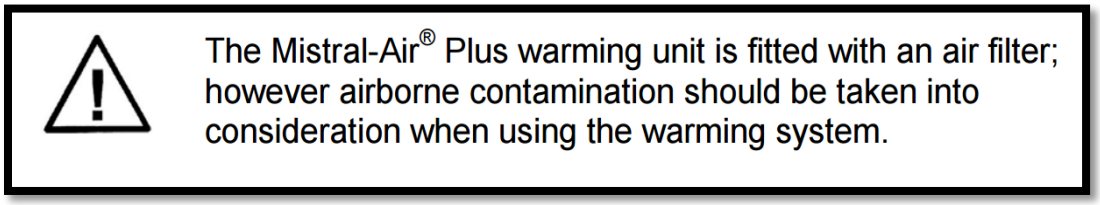
[197] Exhibit 5, Deposition of Corporate Representative Al Van Duren at 313:21; 316:1–15.
[198] *Id.* at 316:8 (emphasis added).
[199] *Id.* at 316:14.
[200] Exhibit 9, Photograph of Bair Hugger Model 200 Warning.

The early Bair Hugger Model 500 featured a similar patient-safety warning:



[201]

While Defendants removed these warnings from all later models of the device, they have not been removed from other patient-warming systems such as Stryker's Mistral-Air:



[202]

Plaintiffs' expert Dr. Yadin David discusses FDA "blue book" guidance documents which instruct device manufactures as to when a warning should be provided: "Include an appropriate warning if there is reasonable evidence of an association of a serious hazard with the use of the device. A causal relationship need not have been proved."[203] Appropriate warnings would have allowed customers to "scrutinize[] the Bair Hugger's effect on operative room airflow" and to consider whether to "curtail the use of the device in high-risk orthopedic implant procedures."[204] The removal of any and all such warnings in spite of Defendants' long-standing knowledge of the attendant risks, demonstrates a

[201] Exhibit 78, Bair Hugger Model 500 Service Manual – 3MBH02237657.
[202] Exhibit A, Report of Dr. Yadin David at 41.
[203] *Id.*
[204] *Id.*

reckless and deliberate disregard for patient safety.[205] *See In re Levaquin*, 2010 WL 7852346, at *10–12 (holding that defendants' "fail[ure] to warn [plaintiff] and his doctor of dangers, despite knowing the particular risks of tendon injury Levaquin posed to seniors using corticosteroids, and the higher risk posed by Levaquin as compared to other [drugs]," constituted *prima facie* evidence that "would provide a jury a basis for punitive damages under Minnesota law"); *In re Mirapex*, 2007 WL 9636345, at *9 (granting plaintiffs' motion to amend complaint to add punitive damages claim because they alleged that defendant had failed "to warn patients about the possible side effect" of the subject drug).

10. Defendants Cannot Challenge the Facts in this Memorandum.

Defendants may offer evidence or argument "to tell a different story, but the question before the Court is whether [Plaintiffs'] evidence, if believed in its entirety, could amount to clear and convincing proof of defendants' deliberate disregard for the right[s] and safety of others." *In re Levaquin*, 2010 WL 7852346, at *10. For example, if Defendants argue that Plaintiffs have mischaracterized or misinterpreted internal documents and employee communications, the Court must disregard such argument. *See id.* at *11 (concluding that defendants' rebuttal of plaintiff's characterizations of employee communications could not deny plaintiff "the opportunity to present his theory to a jury").

Any attempt to rebut the studies discussed in this Memorandum or to question whether Plaintiffs have proven more than an association fall fate to the same mistake. *See id.* (concluding that any "further attempt to invalidate studies cited by [plaintiff] as

[205] *Id.*

methodologically flawed and [to] defend [other studies] as more comprehensive and reliable" are nothing more than "factual disputes [that] should not preclude [plaintiff] from asserting a punitive damages claim"); *In re Mirapex*, 2007 WL 9636345, at *12 (rejecting defendants' assertion that "there has been no evidence of a cause and effect relationship" between the drug and the alleged side effect). In short, this Court should consider Plaintiffs' *prima facie* evidence without "credibility rulings," "cross-examination," or other factual challenge. *See Berczyk*, 291 F. Supp. 2d at 1008 n.3; *see also In re Mirapex*, 2007 WL 9636345, at *14 ("Whether the rebuttal evidence relied upon by Defendants is sufficient to defeat Plaintiffs' claims for punitive damages is an issue for the fact finder at trial.").

CONCLUSION

Plaintiffs have offered *prima facie* evidence of Defendants' deliberate and reckless disregard for patient safety. If fully believed, such evidence would allow a jury to find that:

- Defendants designed and marketed the Bair Hugger without performing any safety validation testing.
- Defendants cut the efficiency of the Bair Hugger filter without validating the safety of the new filters and then hid this change from the FDA and customers.
- Defendants were aware the inadequate filter of the Bair Hugger was causing internal contamination.
- Defendants could have employed design changes that would have mitigated the risk of infection but did not.
- Defendants intentionally disregarded research regarding the potential for the Bair Hugger to cause patient harm through disruption of the surgical field.

- Defendants were aware of the serious weaknesses and limits of prior research supporting the Bair Hugger.
- Defendants engineered and manipulated scientific research to produce commercially favorable results.
- Defendant sought to prevent any serious scientific inquiry into the infection risk from the Bair Hugger.
- Defendants affirmatively misrepresented Bair Hugger safety and failed to warn customers of the risk.

For these reasons, Plaintiffs respectfully move the Court for leave to amend the Master Long Form and Short Form Complaints to include a claim for punitive damages.

Respectfully Submitted,

Dated: April 21, 2017

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